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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/511,284	04/21/2005	Eric Fredericus Bernardus Josephus Mar Thunnissen	13634PCTUS	1854

24392 7590 10/17/2008

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EXAMINER	
WOOLWINE, SAMUEL C	
ART UNIT	PAPER NUMBER
1637	

MAIL DATE	DELIVERY MODE
10/17/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/511,284	THUNNISSEN ET AL.	
	Examiner	Art Unit	
	SAMUEL WOOLWINE	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4 and 10-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *14,16 and 17* is/are allowed.

6)☒ Claim(s) *1,3,10,11 and 15* is/are rejected.

7)☒ Claim(s) *2,4,12 and 13* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☒ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status

Applicant's response submitted 09/17/2007 is acknowledged. Claims 1-4 and new claims 10-17 are pending and under consideration.

The objection to the claims made in OA 03/22/2007 is withdrawn in view of Applicant's amendments.

The rejection under 35 U.S.C. 112, 2nd paragraph, made in OA 03/22/2007 is withdrawn in view of Applicant's amendments.

The rejections under 35 U.S.C. 102(b) and 103(a) made in OA 03/22/2007 are withdrawn in view of Applicant's amendments to recite specific SEQ ID NOS.

New grounds of rejection are set forth below.

It is noted that claims 2 and 4 recite "optional" limitations. Such limitations carry no patentable weight since they are not required by the claim, and will not be further addressed.

Priority

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Europe on April 16, 2002. It is noted, however, that applicant has not filed a certified copy of the 02076494.0 application as required by 35 U.S.C. 119(b).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 10, 11 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is vague and indefinite which HPV types are low-risk, high-risk, or “remaining”. There is no explicit definition as to what strains fall into what category. While page 1 of the specification as filed indicates, for example, types 16, 18, 45, 31 and 33 are "high-risk", this does not allow one to determine the metes and bounds of the claims. For instance, page 1, lines 26-27 of the specification states: “The number of HR-HPV [high-risk HPV] has been expanded in the last years to e.g. 16, 18 45, 31, 33 check.” Hence, the scope of what constitutes a particular risk type is fluid, not definite. It is unclear what Applicant meant by the word “check”.

Furthermore, page 6, lines 11-14 of the specification as filed read as follows: "The terms low and high risk HPV denote a difference in association with the chance of development of malignancy. This has especially for the uterine cervix been described. For high risk is the chance of development of malignancy is higher than for the low risk HPV types." Hence, not only is the scope of what constitutes a particular risk type fluid, it is also subjective and relative.

For purposes of examination over the prior art, *any* HPV types will be considered to qualify as high-risk, low-risk or “remaining” types, with the exception that 16, 18, 45, 31 and 33 will be considered high-risk.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3, 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Manos et al (USPN 5,182,377) in view of:

GenBank GI:397060 [online] August 22, 1993 [retrieved on 09/23/2008] http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?397060:OLDID:456557

GenBank GI:60955 [online] July 6, 1989 [retrieved on 09/23/2008] http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?60955:OLDID:34726

GenBank GI:940299 [online] August 8, 1995 [retrieved on 09/23/2008] http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=940299

GenBank GI:6002612 [online] October 1, 1999 [retrieved on 09/23/2008]

http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?6002612:OLD08:69388

GenBank GI:4103240 [online] January 5, 1999 [retrieved on 09/23/2008]

http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=4103240

GenBank GI:333026 [online] June 2, 1994 [retrieved on 09/23/2008]

http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=333026

GenBank GI:1020266 [online] October 17, 1995 [retrieved on 09/23/2008]

http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=1020266

GenBank GI:1020242 [online] October 17, 1995 [retrieved on 09/23/2008]

http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nuccore&id=1020242

GenBank GI:60295 [online] January 7, 1993 [retrieved on 09/23/2008]

http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?60295:OLDID:34483

GenBank GI:396981 [online] August 22, 1993 [retrieved on 09/23/2008]

http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?396981:OLDID:456547

GenBank GI:333211 [online] February 23, 1994 [retrieved on 09/23/2008]

http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?396981:OLDID:456547

With regard to claim 1, Manos teaches *a method of detecting the presence of HPV in a sample comprising*:

amplifying and labeling part of the E1 HPV gene, wherein amplification is performed a primer pair…to thereby form a labeled fragment (column 14, line 38 through column 15, line 30; column 5, lines 40-45; column 8, line 34 through column 9, line 1; column 3, lines 16-20);

hybridizing the labeled fragment to a solid support upon which a plurality of HPV E1 gene-specific capture probes are immobilized (column 14, line 38 through column 15, line 30; column 5, lines 40-45; column 8, line 34 through column 9, line 1; column 1, lines 46-49);

removing uncaptured labeled fragments (see for example column 7, lines 17-19; column 19, lines 1-3; washing would remove uncaptured labeled fragments);

detecting the captured labeled fragment, wherein detection of the fragment indicates presence of HPV in the sample (see for example column 8, lines 35-40; "determine whether a probe has hybridized to a DNA sequence").

With regard to claim 3, Manos teaches using E1 primers in conjunction with E6/7 primers (see column 15, lines 15-20).

With regard to claim 10, Manos teaches using E1 primers in conjunction with E6/7 primers (see column 15, lines 15-20). This would have necessarily required at least four oligonucleotides (primers), since each amplicon would require two primers (column 3, lines 16-20). Manos teaches typing for types 16, 18 and 33 (high-risk types) and 6 and 11 (which can be considered either low-risk or "remaining" types; see column 1, lines 30-40 and Table 9). Furthermore, Manos expressly teaches it is important to identify and type HPV (column 1, line 38-40).

With regard to claim 11, Manos teaches using E1 primers in conjunction with E6/7 primers (see column 15, lines 15-20). This would have necessarily required at least four oligonucleotides (primers), since each amplicon would require two primers

(column 3, lines 16-20). Furthermore, Manos teaches typing for types 16, 18 and 33 (high-risk types).

Manos teaches the concept of using degenerate primers designed based on regions of known homology such that multiple HPV types are amplified (column 3, lines 32-36; column 5, lines 50-53), followed by identification of the specific type by hybridizing the amplified products to type-specific oligonucleotides (column 5, lines 53-57). This appears to be the basis for Applicant's method as well.

Manos does not teach the specific primer and probe sequences (SEQ ID NOs) recited in claim 1.

The primers recited in claim 1 are degenerate primers based on the HPV E1 gene region. The difference between the claimed invention and the prior art disclosed in Manos is simply in the choice of a particular region of the E1 gene and the choice of primers. Therefore the question to be asked is, were there known HPV sequences that, upon comparison with one another, would have suggested these degenerate primers?

Based on Applicant's specification (paragraphs [0040]-[0041] of the published application), it would appear that Applicant selected the recited primers and probes based on known HPV sequences.

SEQ ID NO:1 is GTGCCAGGAWCAGTTGTTAG, whereas SEQ ID NO:4 is TCYTGYAAHGTCCAHGGYTC. In the case of SEQ ID NO:1, "W" represents either "A" or "T", whereas in the case of SEQ ID NO:4, "Y" represents either "T" or "C", and "H" represents "A", "T" or "C" (see Manos, column 4 for a description of base nomenclature). An alignment of portions of GenBank GI sequences 397060, 60955,

940299, 6002612, 4103240, 333026, 1020266, 1020242, 60295, 396981 and 333211, which were all known at the time the invention was made, indicates conserved nucleotides (*). The region corresponding to SEQ ID NO:1 is indicated with solid underline, whereas the region corresponding to SEQ ID NO:4 is indicated with a dashed underline. As can be seen, these regions were highly conserved, and the differences within these regions accounts for the degenerate bases in SEQ ID NOS:1 and 4. Note that the dashed underline corresponds to the *reverse complement sequence* for SEQ ID NO:4, as that primer corresponds to the complementary strand and would be oriented in the opposite direction to SEQ ID NO:1. Therefore, the degenerate bases are indicated in lower case, e.g. h refers to a base complementary to A, T, or C (i.e. T, A, or G, respectively). Similarly, y refers to a base complementary to T or C (i.e. A or G, respectively). Hence, with regard to claim 1, known HPV sequences would have suggested at least the primer combination SEQ ID NO:1 and 4, since these are found in highly conserved regions.

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gi|397060|emb|X74463.1|            GAGG------ATGGAGAAACTAGCCAGGCGCCTAGATTTGTGCCAGGAAC 2789
gi|60955|emb|X00203.1|             GAGGAAG---ATGGAAGCAATAGCCAAGCGTTTAGATGCGTGCCAGGAAC 2762
gi|940299|gb|L41216.1|PPHE6E       GAGGAAG---ATGGAAGCAATAGCCAAGCGTTTAGATGCGTGCCAGGAAC 2763
gi|6002612|gb|AF092932.1|AF092     GAGGAAG---ATGGAAGCAATAGCCAAGCGTTTAGATGCGTGCCAGGAAC 2763
gi|4103240|gb|AF022227.1|AF022     ----------ATGGAAGCAATAGCCAAGCGTTTAGATGCGTGCCAGGAAC 40
gi|333026|gb|M14119.1|PPH11        GAGGAAG---ATGGAAGCAATAGCCAAGCGTTTAGATGCGTGCCAGGATC 2762
gi|1020266|gb|U31791.1|HPU3179     GAGGACG---ATGGAGACAATAGCCAAGCATTTAGATGTGTGCCAGGAAC 2744
gi|1020242|gb|U31788.1|HPU3178     GAGGACG---ATGGAGACAATAGCCAAGCATTTAGATGTGTGCCAGGAAC 2744
gi|60295|emb|X62843.1|             GAGGACG---ATGGAGACAATAGCCAAGCATTTAGATGCGTGCCAGGAAC 2764
gi|396981|emb|X74475.1|            GAGGAAGAAAATGGAGACACTGGCCAAACGTTTAGATGCGTGCCAGGAAC 2759
gi|333211|gb|M73236.1|PPHPAPV4     GAGGAAGACTATGGAGAGACTGGCCAAACGTTTAGATGCGTGCCAGGAAC 2741
                                          *****     * ****  *   *****  *********W*

gi|397060|emb|X74463.1|            AGTTGTTAGAACTTTATGAACAAGACAGCAAACAGCTACAGCACCATATA 2839
gi|60955|emb|X00203.1|             AGTTGTTAGAACTTTATGAAGAAAACAGTACTGACCTACACAAACATGTA 2812
gi|940299|gb|L41216.1|PPHE6E       AGTTGTTAGAACTTTATGAAGAAAACAGTACTGACCTAAACAAACATGTA 2813
gi|6002612|gb|AF092932.1|AF092     AGTTGTTAGAACTTTATGAAGAAAACAGTACTGACCTAAACAAACATGTA 2813
gi|4103240|gb|AF022227.1|AF022     AGTTGTTAGAACTTTATGAAGAAAACAGTACTGACCTAAACAAACATGTA 90
gi|333026|gb|M14119.1|PPH11        AGTTGTTAGAACTTTATGAAGAAAACAGTATTGATATACACAAACACATT 2812
gi|1020266|gb|U31791.1|HPU3179     AGTTGTTAGAACTGTATGAAGAAAATAGTAATAACCTTACAAAACATATA 2794
gi|1020242|gb|U31788.1|HPU3178     AGTTGTTAGAACTGTATGAAGAAAATAGTAATAAACTTACAAAACATATA 2794
gi|60295|emb|X62843.1|             AGTTGTTAGAACTGTATGAAGAAAATAGTAATGAACTTAAAAAACATATA 2814
gi|396981|emb|X74475.1|            AGTTGTTAGAACTGTATGAGGAAGATAGTAAACATTTAGAAAAACATGTG 2809
gi|333211|gb|M73236.1|PPHPAPV4     AGTTGTTAGAACTGTATGAGGAAAATAGTAGGGATTTACAAAAACATATT 2791
                                   ************* *****  ** * ** *   *  *     * **  *
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gi|397060|emb|X74463.1|          TTGCACTGGAAATATATACGTTATGAAAGTGTAATATATTATACAGCAAG 2889
gi|60955|emb|X00203.1|           TTGCATTGGAAATGCATGAGACATGAAAGTGTATTATTATATAAAGCAAA 2862
gi|940299|gb|L41216.1|PPHE6E     TTGCATTGGAAATGCATGAGACATGAAAGTGTATTATTATATAAAGCAAA 2863
gi|6002612|gb|AF092932.1|AF092   CTGCATTGGAAATGCATAAGACATGAAAGTGTATTATTATATAAAGCAAA 2863
gi|4103240|gb|AF022227.1|AF022   CTGCATTGGAAATGCATAAGACATGAAAGTGTATTATTATATAAAGCAAA 140
gi|333026|gb|M14119.1|PPH11      ATGCATTGGAAATGCATACGATTGGAAAGTGTATTACTACACAAAGCAAA 2862
gi|1020266|gb|U31791.1|HPU3179   CAACATTGGAAATGCATAAGATATGAATGTGTGTTATTACACAAAGCAAA 2844
gi|1020242|gb|U31788.1|HPU3178   CAACATTGGAAATGTATACGATATGAATGTGTGTTACTACACAAAGCTAA 2844
gi|60295|emb|X62843.1|           CAACATTGGAAATGCTTAAGGTACGAAAGTGTACTCTTACACAAAGCACG 2864
gi|396981|emb|X74475.1|          CAGCACTGGAAGTGTTTACGCATAGAAGCAGCCTTATTATTTAAGGCTCG 2859
gi|333211|gb|M73236.1|PPHPAPV4   GAACATTGGAAATGTTTACGTATGGAGGCAGTGGTATTGTATAAGGCCCG 2841
                                    ** ***** *   *  *    **    *   *       *  **

gi|397060|emb|X74463.1|          ACAAATGGGCATTAAACGTCTGGGCCACCAGGTGGTGCCAAGTTTAGATG 2939
gi|60955|emb|X00203.1|           ACAAATGGGCCTAAGCCACATAGGAATGCAAGTAGTGCCACCATTAAAGG 2912
gi|940299|gb|L41216.1|PPHE6E     ACAAATGGGCCTAAGCCACATAGGAATGCAAGTAGTGCCACCATTAAAGG 2913
gi|6002612|gb|AF092932.1|AF092   ACAAATGGGCCTAAGCCACATAGGAATGCAAGTAGTGCCA***CCATTAAAGG*** 2913
gi|4103240|gb|AF022227.1|AF022   ACAAATGGGCCTAAGCCACATAGGAATGCAAGTAGTGCCACCATTAAAGG 190
gi|333026|gb|M14119.1|PPH11      ACAAATGGGCCTGAGCCACATCGGGTTACAAGTAGTACCA***CCATTAACTG*** 2912
gi|1020266|gb|U31791.1|HPU3179   GCAAATGGGCCTAAACCACATTGGAATGCAAGTGGTGCCAGCATTAACAG 2894
gi|1020242|gb|U31788.1|HPU3178   GCAAATGGGCCTGAACCACATTGGAATGCAAGTGGTGCCAGCATTAGCAG 2894
gi|60295|emb|X62843.1|           CCAAATGGGCCTAAGCCACATTGGATTACAAGTGGTGCCACCATTGACAG 2914
gi|396981|emb|X74475.1|          TGAAATGGGCTATGCACAAGTAGGACATCAAATAGTGCCAGCACTGGAAA 2909
gi|333211|gb|M73236.1|PPHPAPV4   TGAAATGGGCTTTGCAAATATAGGACATCAAATAGTACC***AACATTGGAAA*** 2891
                                   ********          * **    **  * ** ***    *

gi|397060|emb|X74463.1|          TGTCAAAAGCCAAAGCCCATGCAGCAATTGAAATGCAAATGTGTCTAGAA 2989
gi|60955|emb|X00203.1|           TGTCCGAAGCAAAAGGACATAATGCCATTGAAATGCAAATGCATTTAGAA 2962
gi|940299|gb|L41216.1|PPHE6E     TGTCCGAAGCAAAAGGACATAATGCCATTGAAATGCAAATGCATTTAGAA 2963
gi|6002612|gb|AF092932.1|AF092   ***TGTCCGAAGC***AAAAGGACATAATGCCATTGAAATGCAAATGCATTTAGAA 2963
gi|4103240|gb|AF022227.1|AF022   TGTCCGAAGCAAAAGGACATAATGCCATTGAAATGCAAATGCATTTAGAA 240
gi|333026|gb|M14119.1|PPH11      ***TGTCAGAGAC***TAAAGGACATAATGCTATTGAAATGCAAATGCATTTAGAA 2962
gi|1020266|gb|U31791.1|HPU3179   TGTCACAGACAAAGGGACACCAGGCCATTGAAATGCAAATGACATTAGAA 2944
gi|1020242|gb|U31788.1|HPU3178   TGTCACAGACAAAGGGACACCAGGCAATTGAAATGCAAATGACATTAGAA 2944
gi|60295|emb|X62843.1|           TATCACAAGCTAAGGGACATGAGGCAATTGAAATGCAAATGACTTTAGAG 2964
gi|396981|emb|X74475.1|          TATCCAGGGCCAAGGCCCACGTTGCAATTGAAATTCAATTGGCGTTAGAG 2959
gi|333211|gb|M73236.1|PPHPAPV4   ***CATGTAGAG***CCAAGGCCCACATGGCAATTGAAATACACTTGGCATTAGAG 2941
                                   *      * ** *  **    ** ******** **  **    ****

gi|397060|emb|X74463.1|          TCTTTGCAAACTACTGAATATAACTTAGAGCCATGGACGTTACAGGACAC 3039
gi|60955|emb|X00203.1|           TCATTATTAAGGACTGAGTATAGTATGGAACCGTGGACATTACAAGAAAC 3012
gi|940299|gb|L41216.1|PPHE6E     TCATTATTAAAGACTGAGTATAGTATGGAACCGTGGACATTACAAGAAAC 3013
gi|6002612|gb|AF092932.1|AF092   TCATTATTAAAGACTGAGTATAGTATGGAACCGTGGACATTACAAGAAAC 3013
gi|4103240|gb|AF022227.1|AF022   TCATTATTAAAGACTGAGTATAGTATGGAACCGTGGACATTACAAGAAAC 290
gi|333026|gb|M14119.1|PPH11      TCCTTAGCAAAAACTCAGTATGGTGTGGAACCTTGGACATTACAGGACAC 3012
gi|1020266|gb|U31791.1|HPU3179   ACACTATTAAACTCTGACTATGGTATGGAACCATGGACATTGCAAGACAC 2994
gi|1020242|gb|U31788.1|HPU3178   ACATTACTAAACTCTGACTATGGTACGGAACCATGGACATTGCAAGAGAC 2994
gi|60295|emb|X62843.1|           ACATTACTAGAGTCTGAGTTTGGTATGGAACCATGGACTTTACAAGATAC 3014
gi|396981|emb|X74475.1|          ACATTATTGCAGTCCACATTTGGTACAGAACCATGGACATTGCAAGAGAC 3009
gi|333211|gb|M73236.1|PPHPAPV4   ACATTATTGCAGTCCTCGTATGGTAAAGAACCATGGACATTGCAAGAAAC 2991
                                  *  *        *    * *      **y**h*****h**y**y** **
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It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to modify the methods and kits of Manos in accordance with known HPV sequences such as the recited GenBank GI numbers to arrive at a primer pair of SEQ ID NO:1 and 4 (thus meeting the limitations of claim 1)

since the known sequences indicate these are regions highly conserved among a number of HPV types. Note that Manos taught the concept of using degenerate primers based on regions of known homology to amplify multiple HPV types (column 3, lines 32-36; column 5, lines 50-53), followed by identification of the specific type by hybridizing the amplified products to type-specific oligonucleotides (column 5, lines 53-57). One of ordinary skill in the art would have recognized the difference between the claimed invention and the methods/kits of Manos as simply choosing obvious alternative conserved and regions in which to design the primers.

Conclusion

Claims 2, 4, 12 and 13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 14, 16 and 17 are allowed. These claims require the use of probes selected from the group consisting of SEQ ID NO:24-59. Each of these probes has an identical spacer sequence at the 5' end: TTTTCTTTTCTTTTC. There is not teaching or suggestion of this particular spacer sequence in the prior art.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SAMUEL WOOLWINE whose telephone number is (571)272-1144. The examiner can normally be reached on Mon-Fri 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Samuel Woolwine/
Examiner, Art Unit 1637

/GARY BENZION/
Supervisory Patent Examiner, Art Unit 1637